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DEA/FCE-1994

SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
08/711,961	09/06/96	BRANSTROM	A 003/030/SAP

MCMR-JA (JOHN MORAN)
US ARMY MEDICAL RESEARCH
AND MATERIEL COMMAND
FORT DETRICK
FREDERICK MD 21702-5012

HM22/0719

EXAMINER	
RAILEY, J	
ART UNIT	PAPER NUMBER
	19

DATE MAILED 36

07/19/99

Please find below a communication from the EXAMINER in charge of this application
Commissioner of Patents

Office Action Summary

Application No.
08/711,961

Applicant(s)
Branstrom et al.

Examiner
J. Railey

Group Art Unit
1636

☒ Responsive to communication(s) filed on 8 Jul 1999

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 45-55 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 45-55 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 18

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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The request filed on 8 July 1999 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 08/711,961 is acceptable and a CPA has been established. An action on the CPA follows.

Claims 45-55 are currently pending. Applicant's preliminary amendment of 8 July 1999 canceled claims 1-27 and 34-43

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 45-55 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-17 of U.S. Patent No. 5,824,538. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant application claims methods for delivery of exogenous DNA capable of being expressed in an animal cell, while the patent claims are drawn to similar methods for mammalian cells, as well as the delivery vehicles for such methods. The claims in the instant application are obvious over the claims in the patent.

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 45-55 are rejected under 35 U.S.C. 102(e) as being anticipated by Powell et al.

[U.S. Patent 5,877,159].

Applicant has submitted an Information Disclosure Statement, filed 8 July 1999, and provided a copy of the U.S. Patent 5,877,159 issued to Powell et al. on 2 March 1999. This patent has priority to 3 May 1995, which has a priority earlier than the priority of 6 September 1995 granted to the instant application. Powell et al. broadly disclose and claim delivery of "live invasive bacteria" which comprise a "eukaryotic expression cassette encoding genes." The purpose of the "eukaryotic expression cassette" is that the animal cell infected by the invasive bacteria will express the cassette and produce an antigen which acts as a vaccine. This is exactly the same concept used by applicant in the instant application "for the delivery of exogenous DNA capable of being expressed in an animal cell," and the reason why applicant argued that the invention of the instant application was patentable over the prior art of already of record in the file. In addition, Powell et al. suggest the use of attenuation mutations in the live invasive bacteria. See column 8 beginning at line 61. Particularly, at column 24, Example 4 the Δ asd

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mutation which results in lysis of the prokaryotic host cell in the absence of DAP (the condition inside the eukaryotic host cell) is explicitly taught in *S. flexneri*. This is exactly the invention disclosed, exemplified and claimed both broadly and specifically by applicant. Powell et al. anticipate applicant's claimed invention.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Art Unit 1636 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number for Art Unit 1636 is (703) 308-4242 or 305-3014.

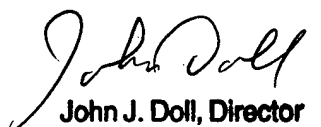
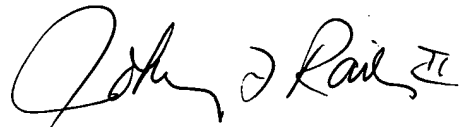
Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. F. Railey, whose telephone number is (703) 308-0281. The examiner can normally be reached on Monday-Thursday, and alternate Fridays, from 8:00 AM-5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, George Elliott, can be reached at (703) 308-4003. The fax phone number for informal transmissions to the examiner is (703) 305-7939.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

15 July 1999

JOHNNY F. RAILEY II, PH.D.
PRIMARY EXAMINER
TECHNOLOGY CENTER 1600



John J. Doll, Director
Technology Center 1600